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Re-evaluation Decision

Dithiopyr

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Re-evaluation Decision for Dithiopyr

After a re-evaluation of the herbicide dithiopyr, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting continued registration of products containing dithiopyr for sale and use in Canada.

An evaluation of available scientific information found that under the revised conditions of use, products containing dithiopyr have value and do not present unacceptable risks to human health or the environment. As a condition of the continued registration of dithiopyr, new risk-reduction measures must be included on the labels of all products. No additional data are being requested at this time.

The regulatory approach regarding the re-evaluation of dithiopyr was first presented in the consultation document[1] Proposed Re-evaluation Decision PRVD2009-01, *Dithiopyr*. This Re-evaluation Decision[2] describes this stage of the PMRA's regulatory process concerning the re-evaluation of dithiopyr and summarizes the Agency's decision and the reasons for it. No comments were received during the consultation process. This decision is consistent with the proposed re-evaluation decision stated in PRVD2009-01. To comply with this decision, registrants of products containing dithiopyr will be informed of the specific requirements affecting their product registration(s) and of the regulatory options available to them.

For more details on the information presented in this Re-evaluation Decision, please refer to the Science Evaluation in PRVD2009-01.

What Does Health Canada Consider When Making a Re-evaluation Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions or proposed conditions of registration.[3] The Act also requires that products have value[4] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies rigorous, modern hazard and risk assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in both humans (for example, children) and organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties present when predicting the impact of pesticides.

For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Health Canada's website at healthcanada.gc.ca/pmra.

What is Dithiopyr?

Dithiopyr is a selective turf herbicide. It is registered for pre-emergence and early postemergence control of crabgrass (large or smooth) on turf in Ontario and Quebec. Dithiopyr is to be applied once per year with ground equipment including hose, handgun or boom sprayer by trained and certified applicators.

Health Considerations

Can Approved Uses of Dithiopyr Affect Human Health?

Dithiopyr is unlikely to affect your health when used according to the revised label directions.

Potential exposure to dithiopyr may occur through the drinking water, when handling and applying the product or when entering treated areas such as residential turf and golf courses. When assessing health risks, two key factors are considered: the levels at which no health effects occur in animal testing and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when dithiopyr products are used according to label directions.

Dithiopyr induced mild but transient eye and dermal irritation in rabbits and was not a sensitizer in guinea pigs. Consequently, no statements are required on the label of the technical product.

Dithiopyr did not cause cancer in animals, was not genotoxic or teratogenic and showed no signs of neurotoxicity. The liver and kidneys were the main targets of toxicity by the oral route in mice, rats and dogs. Effects on liver weights were also seen following exposure via the dermal route in rats. There is a low level of concern for potential prenatal and postnatal toxicity associated with dithiopyr.

The risk assessment protects against these effects by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Residues in Water

Dietary risks from water are not of concern.
As dithiopyr is not registered for use on food, exposure and risk from food consumption is considered negligible. Reference doses define levels to which an individual can be exposed over a single day (acute) or lifetime (chronic) and expect no adverse health effects. Generally, dietary exposure from food and water is acceptable if it is less than 100% of the acute reference dose or chronic reference dose (acceptable daily intake). An acceptable daily intake is an estimate of the level of daily exposure to a pesticide residue that, over a lifetime, is believed to have no significant harmful effects.

Human exposure to dithiopyr was estimated from residues in drinking water and ranged from 6.5% of the acceptable daily intake for the general population to 21.2% of the acceptable daily intake for infants. An acute drinking water assessment was not performed as no acute endpoints were identified, due to the low acute toxicity of dithiopyr.

Risks in Residential and Other Non-Occupational Environments

Non-occupational risks are not of concern
Risks to homeowners applying the domestic product are not of concern. Postapplication risks to adults, youths and children entering treated lawns and turf following commercial and homeowner application are not of concern.

Aggregate risks are not of concern.
Aggregate risks to homeowners and children from drinking water and residential exposures are not of concern.

Occupational Risks from Handling Dithiopyr

Occupational risks are not of concern.
Risk estimates associated with applying, mixing and loading activities are not of concern and additional personal protective equipment are not required beyond what is currently specified on the label.

Postapplication risks are not of concern.
Risks to workers re-entering turf treated with dithiopyr are not of concern. The minimum 12 hour restricted-entry interval is required for all uses, with the exception of golf courses where entry is restricted until after the spray has dried.

Environmental Considerations

What Happens When Dithiopyr is Introduced Into the Environment?

Dithiopyr poses a potential risk to terrestrial and aquatic plants; therefore, additional risk-reduction measures need to be observed.

When dithiopyr is released into the environment, some of it can be found in soil and surface water. However, dithiopyr readily volatilizes from turf grass, is broken down by soil microbes and undergoes phototransformation in water. Thus, dithiopyr is not expected to persist in the environment. Laboratory and field studies indicate that dithiopyr is not mobile in soil. There is limited potential for leaching and groundwater contamination and runoff can occur, although the concentrations are low.

When dithiopyr is used for weed control in turf grass, there is a potential that non-target plant species on land and in water may be exposed to the chemical as a result of spray drift or runoff. Some of plant species are sensitive to the chemical and would be adversely affected. To minimize the potential exposure, strips of land between the agricultural field and the nontarget terrestrial or aquatic areas must be left unsprayed. The width of these buffer zones must be specified on the product label. Dithiopyr presents negligible risk to wild birds and mammals, bees and other arthropods. Dithiopyr poses risk to terrestrial plants and aquatic organisms like fish, amphibians and algae. The concentrations are very low in runoff and do not pose a concern for aquatic environments.

Value Considerations

What is the Value of Dithiopyr?

Dithiopyr controls crabgrass in turf.

Crabgrass is a troublesome weed in turf. Dithiopyr provides both pre-emergence and early postemergence control of crabgrass in established turf. It provides a wider application window than alternative crabgrass control products used on turf. In addition, the application rate of dithiopyr is usually lower than that of alternative crabgrass control products.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of dithiopyr, the PMRA is requiring further risk-reduction measures for product labels.

Additional Key Risk-Reduction Measures

Human Health

- Additional label statements to clarify the maximum number of applications per year
- A restricted-entry interval to protect workers entering treated sites

Environment

- Precautionary statements and buffer zones to protect non-target terrestrial and aquatic habitats and terrestrial and aquatic habitats that may contain sensitive species

Other Information

The risk assessments found in the PRVD2009-01, *Dithiopyr*, serves as an evaluation report. The relevant test data on which the re-evaluation decision is based on are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa, ON, Canada). For more information, please contact the PMRA's Pest Management Information Service.

Any person may file a notice of objection[5] regarding this decision on dithiopyr within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website (Request a Reconsideration of Decision, www.hc-sc.gc.ca/cps-spc/pest/protect-proteger/publi-regist/index-eng.php#rrd), or contact the PMRA's Pest Management Information Service.

[5] As per subsection 35(1) of the *Pest Control Products Act*.